MAR 1 4 2014 K133323

510(K) SUMMARY

SPONSOR:	Volcano Corporation 3721 Valley Center Drive San Diego, CA 92130
CONTACT:	Neeta Sharma Director, Regulatory Affairs Volcano Corporation 3721 Valley Center Drive San Diego, CA 92130 Tel: (858) 720-4187 Fax :(858) 720-0335
DATE PREPARED:	March 12, 2014
DEVICE:	Volcano iFR® Modality
TRADE NAME:	Volcano iFR® Modality
COMMON NAME:	Ultrasonic Pulsed Echo Imaging System
CLASSIFICATION:	21 CFR Part 892.1560 IYO: System, Imaging, Pulsed Echo, Ultrasonic Class II Device
PREDICATE DEVICE:	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System (K123898)
DEVICE DESCRIPTION:	The Volcano iFR® Modality is new software that calculates blood pressures in the coronary and peripheral vasculature through isolation of the cardiac wave cycle where intracoronary resistance is naturally constant and minimized and where intracoronary flow is maximized. This results in the ability to measure pressure without the administration of a hyperemic agent. Pressure measurement is captured through the use of currently marketed pressure wires compatible with the currently marketed s5/s5i/CORE/CORE Mobile imaging and pressure measurement system.
INTENDED USE:	The Volcano s5™/s5i/CORE/CORE™ Mobile Precision Guided Therapy System is used for the qualitative and quantitative evaluation of vascular morphology in the

	coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures. The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures
COMPARISON OF CHARACTERISTICS:	The proposed device the same as the currently marketed device with the exception of software. There are no changes to the pressure measurement wires for collection of data using the iFR® Modality.
PERFORMANCE DATA:	Performance testing completed for a determination of substantial equivalence included the following: • Software Validation • Repeatability and Reproducibility of measurements • Clinical Data

One primary clinical study was used to provide clinical data in support of the iFR® modification. ADVISE II (Adenosine Vasodilator Independent Stenosis Evaluation) was a prospective, observational, non-randomized, double blind, global, multi-center registry sponsored by Volcano Corporation investigating the diagnostic utility of iFR in assessing coronary stenosis relevance (NCT01740895). The purpose of this registry was to assess the clinical value of iFR to characterize, without concomitant administration of hyperemic agents and outside a specified range of iFR values, coronary stenosis severity as determined with fractional flow reserve (FFR).

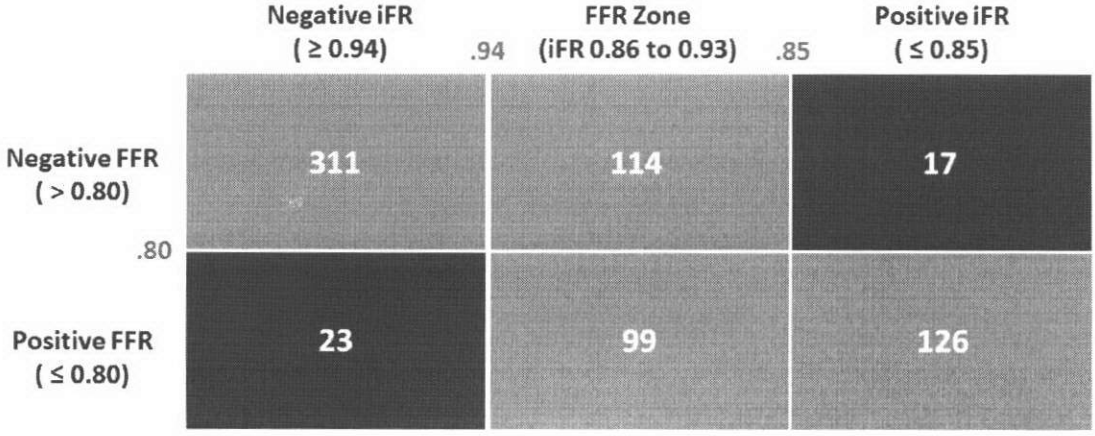
In ADVISE II, data were obtained in patients with coronary stenoses between 40-90% by visual assessment on angiography. These lesions were interrogated by FFR assessment with a Volcano Corporation pressure wire. A per lesion analysis was recorded with both baseline and hyperemic measurements. The baseline recording was used to calculate iFR at the core lab using the HARVEST software (investigators were blinded to the iFR results). This iFR value was compared with the FFR value measured in the same recording during maximal hyperemia. The FFR assessment was obtained using standard guidelines for the FFR procedure with the patient's heart being functionally stressed by a hyperemic agent called adenosine at 140 mcg/kg/min.

Study Results

Of the 690 lesions assessed in the ADVISE II analysis the patient characteristics were: mean age was 63.6 + 10.8, 68.8% were Male, 77.9% with Hypertension, 34.6% had Diabetes, 21.6% were

Smokers and 33.9% had a prior MI. The clinical presentations of the patients varied with the majority (50.3%) presenting with stable angina and 25.4% presenting with unstable angina. 18.4% of patients had presented with myocardial ischemia in a non-invasive stress test, 3.3% presenting with a STEMI that was more than 48 hours, 5.5% presenting with an NSTEMI more than 48 hours and 7.7% deemed "Other."

The counts provided in the cells of the below 2x3 matrix were provided by the study core laboratory. The Hybrid approach specifies that, for iFR values between and including 0.86 and 0.93, FFR is performed to determine lesion category. Hence, the 114 lesions in the top cell of the center column are categorized as "negative" because FFR is >0.80; conversely, the 99 lesions in the bottom cell of the center column are categorized as "positive" because FFR is ≤ 0.80.



Two hundred and forty eight (248) lesions were ischemic as determined by the reference method (FFR ≤ 0.80); of these 225 were properly categorized by the Hybrid method; there were 23 false negatives. Four hundred and forty two (442) lesions were not ischemic as determined by the reference method (FFR > 0.80); of these, 425 were properly categorized by the Hybrid method; there were 17 false positive lesions.

The overall accuracy of sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy were:

Parameter	Estimate	95% CI
Sensitivity	90.7% (225/248)	[86.4%, 94.0%]
Specificity	96.2% (425/442)	[93.9%, 97.7%]
Positive Predictive Value	93.0% (225/242)	[89.0%, 95.9%]
Negative Predictive Value	94.9% (425/448)	[92.4%, 96.7%]
Diagnostic Accuracy	94.2% (650/690)	[92.2%, 95.8%]

Note: All iFR values falling within the FFR Zone were deferred to FFR for determination of treatment and were therefore accounted for as true positives or true negatives per FFR criteria.

These lesions (or patients) represent the group that is not spared from hyperemic agent when using the hybrid iFR/FFR approach.
The iFR Hybrid Approach Analysis performed on the independently-held ADVISE II dataset, was the first prospective, real world registry comparing iFR and FFR and demonstrated a statistically high correlation (sensitivity 90.7% for FFR less than or equal to 0.80, specificity 96.2% for FFR greater than 0.80). The hybrid method would have avoided the need to use a hyperemic agent in 65.1% of this patient population.

Parameter	Percentage Free From Hyperemic Agent	95% CI
Lesions free from Adenosine	69.1% (477/690)	[65.5%, 72.6%]
Patients free from Adenosine	65.1% (389/598)	[61.1%, 68.9%]

- The ADVISE II study illustrated a 5.8%, i.e., (17+23)/690, classification discordance between the iFR Hybrid Approach and FFR. Among 477 lesions that would be assessed without hyperemia by the iFR Hybrid Approach, 40 (17+23) were due to classification discordance.
- Lesion is free from Adenosine if iFR ≤ 0.85 or iFR ≥ 0.94
- Patient is free from Adenosine if all of his/her lesions are free from Adenosine
- Excludes patients for whom no iFR value is available

The results of the performance data demonstrate equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

Volcano Corporation
Neeta Sharma
Regulatory Affairs Director
3721 Valley Centre Drive, Suite 500
San Diego, CA 92130

Re: K133323
Trade/Device Name: Volcano iFR Modality
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO
Dated: February 7, 2014
Received: February 10, 2014

Dear Ms. Sharma,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

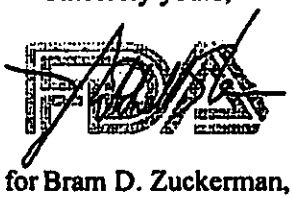
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K133323

Device Name Volcano iFR® Modality

Indications for Use

The iFR® Modality of the s5/s5i/CORE/CORE Mobile Precision Guided Therapy System is indicated in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures. The iFR® Modality is intended to be used in conjunction with currently marketed Volcano pressure wires.

Prescription Use ___X___ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.03.14 07:40:01 -04'00'
for Bram Zuckerman